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IN THE UNITED STATES DISTRICT COURT

DISTRICT OF UTAH, CENTRAL DIVISION

GELT TRADING, LTD., a Cayman Islands limited company, Plaintiff, v. CO-DIAGNOSTICS, INC., a Utah Corporation, DWIGHT EGAN, JAMES NELSON, EUGENE DURENARD, EDWARD MURPHY, RICHARD SERBIN, REED BENSON, BRENT SATTERFIELD, Defendants.	Case No. 2:20-cv-00368-CMR **PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS**

Lead Plaintiff Gelt Trading, Ltd. ("Gelt"), through undersigned counsel, submits this memorandum in opposition to the Defendants Motion to Dismiss [Dkt. No. 91] the Plaintiff's Second Amended Complaint (the "Complaint") [Dkt. No. 86]

INTRODUCTION

Plaintiff brought this securities class action on behalf of shareholders in Defendant Co-Diagnostics, Inc. ("Co-Diagnostics"), a diagnostic testing company, who lost hundreds of millions of dollars in share value. These massive investor losses stemmed from misleading statements by Defendant Co-Diagnostics and its Chief Science Officer, Defendant Brent Satterfield, regarding the purported 100% accuracy of Co-Diagnostics' Covid-19 test. This lawsuit seeks to hold Co-Diagnostics and its key executives accountable for a fraud on the investing public.

Prior to the Covid-19 pandemic, Co-Diagnostics was a struggling start-up diagnostic testing company. Its shares traded at less than $1 and it was in danger of being delisted from the NASDAQ stock exchange. Things changed when the pandemic struck. Co-Diagnostics developed a Covid-19 diagnostic test and received FDA Emergency Use Authorization to sell the tests. Co-Diagnostics immediately entered into lucrative contracts with multiple state governments and supplied its tests to over 50 countries. Its share price soared.

However, on April 30, 2020, still near the outset of the pandemic, the first of several news reports surfaced questioning the accuracy of Co-Diagnostics' Covid-19 tests. It appeared that Co-Diagnostics' tests severely *under-detected* Covid-19 positive patients—a crucial problem because a high incidence of false positives undermined confidence in the efficacy of the tests and can create, as some experts have stated, a "public health disaster". Co-Diagnostics' response to this crisis is the basis for this fraud case. Rather than disclose the very serious problems with its Covid-19 test, Co-Diagnostics' version of damage control was to falsely convey the impression to the

public and its investors that its test was actually 100% accurate—in other words, basically perfect. That message was false and a fraud on investors, because Co-Diagnostics knew its tests had accuracy issues and because no diagnostic test is 100% accurate.

Co-Diagnostics conveyed that misleading message twice: first, through Satterfield's statements to the press and, second, more importantly, through a misleading company press release. Relying on these false statements and believing that Co-Diagnostics had developed a market-beating, uniquely accurate test, the investing public bought more shares of Co-Diagnostics, driving its price up to almost $30 a share (and giving the company a market capitalization of over $800 million). But Co-Diagnostics' fraud came to light two weeks later, when additional news reports confirmed that Co-Diagnostics' test had accuracy issues. The markets pummeled the company's share price based on this news, as the stock dropped almost 50% in a day. The net result: investor losses in the hundreds of millions of dollars. This action—alleging that the Defendants violated the federal securities laws through their misleading statements—is brought on behalf of Co-Diagnostics' defrauded investors, to compensate them for these significant losses.

The Defendants' motion to dismiss should be denied, as their arguments are baseless ***First***, the Defendants try to hide behind the purported literal truth of the press release, contending that it only addressed the "100% accuracy" of its tests in some limited performance data. But the law requires that the Court look to the context of the statements. It does not permit the Defendants to tell the investing public half-truths that misinform and mislead investors. Here, the Defendants' statements made to investors, taken together and in context, misled investors by conveying a false impression that Co-Diagnostics' tests were 100% accurate and by omitting key information (regarding problems with the tests) undermining that false impression.

Second, contrary to Defendants' contentions, the Plaintiff is not proceeding under a "duty-

to-correct" theory, where a defendant has a duty to correct a statement that is later revealed to be inaccurate. This is not that type of case. The putative class brought a direct fraud case, because the Defendants knowingly misled investors when they made the misstatements at issue.

Third, the Plaintiff has more than satisfied its burden to plead scienter. As alleged, the Defendants knew Co-Diagnostics' tests had accuracy problems *before* they falsely conveyed the tests were 100% accurate. And the timing and obvious motive—damage control based upon negative revelations about the tests—clearly supports a strong inference of scienter. Indeed, the Defendants have not submitted a competing non-culpable inference of scienter. That is because the facts all point in the same direction: the Defendants intended to deceive or were reckless.

In sum, the Court should deny the motion to dismiss and allow this case to proceed.

FACTUAL BACKGROUND[1]

A. Defendant Co-Diagnostics, a Struggling Start-Up Company, Finds Opportunity Amidst the COVID-19 Pandemic.

In early 2020, the COVID-19 global pandemic began to spread across the world, resulting in a public health crisis that had not been seen for at least a century. SAC ¶ 1. Federal and State governments realized that the only way to contain the spread was to use mass testing for the Covid-19 virus on a broad public scale. *Id.* ¶ 2. Defendant Co-Diagnostics, a publicly traded company that had never before sold diagnostic tests in the United States, sought to capitalize on the dire and

[1] These facts are taken from the allegations in the Complaint and must be accepted as true for purposes of this motion. Additionally, the facts are also drawn from the news articles cited in Plaintiff's complaint. Where, as here, a complaint relies on documents to make its claims, a court may consider those documents, including news articles. *GFF Corp. v. Associated Wholesale Grocers, Inc.*, 130 F.3d 1381, 1384-85 (10th Cir. 1997); *In re SunEdison, Inc. Securities Litigation*, 300 F. Supp. 3d 444, 487 n. 7 (S.D.N.Y. 2018); *Evanston Police Pension Fund v. McKesson Corporation*, 411 F. Supp. 3d 580, 593 (N.D. Cal. 2019).

immediate need to administer potentially hundreds of millions of Covid-19 diagnostic tests. *Id*. ¶ 4-5.

In the prospectus attached to its SEC Form S-1 registration statement, filed on April 28, 2017, Co-Diagnostics stated that its primary revenue source was from selling diagnostics tests for Zika Virus, Tuberculosis, Hepatitis B, Hepatitis C, Malaria, Dengue Fever, and HIV to customers primarily located in the Caribbean, Central and South America, North America, and India. *Id*. ¶44. Before the pandemic, within the United States, Co-Diagnostics only sold tests for use in agriculture and mosquito abatement. *Id*. ¶ 44-46. It did not have FDA approval to sell any diagnostic clinical diagnostic tests in the U.S.

And the company was struggling financially. The stock closed at $0.8952 per share on December 31, 2019—a few months before the pandemic arrived in the United States in large numbers. *Id.* Co-Diagnostics was in danger of being delisted from the NASDAQ, which requires that companies not trade below $1.00 per share to continue being listed on the exchange. *Id.* ¶48.

That all changed when the pandemic hit. Within a few days, Co-Diagnostics developed a diagnostic test for COVID-19 and received regulatory approval to sell in Europe. SAC ¶¶ 50-52. It was also the first company to receive approval from the Food and Drug Administration ("FDA") under Emergency Use Authorization. *Id.* ¶ 54. Co-Diagnostics rushed its product to market because it had competition among larger competitors; it sought to distinguish itself by being the first (and allegedly best) test. *Id.* ¶¶ 52-56. Notably, Co-Diagnostics' share price started to dramatically rise on the news that it had an approved Covid-19 test. *Id.* ¶¶ 53-55.

B. Co-Diagnostics Emerges as an Early Market Leader in State and Federal Testing.

In March 2020, three state governments chose to use Co-Diagnostics' diagnostic test for their statewide Covid-19 testing—Utah, Iowa, and Nebraska. *Id.* ¶¶ 58, 82. These contracts were lucrative for Co-Diagnostics, ranging from $5 million to over $20 million. *Id.* ¶ 58. Quickly, and

in addition to supplying these state-sponsored tests, Co-Diagnostics began supplying Covid-19 tests to 50 countries and 12 different states in various capacities. *Id.* ¶ 57. These developments made the company an overnight success, and the investing public responded by purchasing stock, sending Co-Diagnostics' share price soaring. *Id.* ¶¶ 53-55. By the end of April 2020, the company's stock was pushing towards $20 per share, which would be a gain of more than 2,000 percent compared to the beginning of the year. *Id.* ¶ 53, Ex. D (December 2, 2020 NPR Article).

C. Reports Surface Questioning the Accuracy of Co-Diagnostics' Tests.

On April 30, 2020, The Salt Lake Tribune published an article titled "'This is a Potential Public Health Disaster': COVID-19 results from TestUtah.com are raising questions." (the "Tribune Article"). *Id.* ¶ 59, Ex. A (April 30, 2020 Salt Lake Tribune Article). The article questioned the accuracy of Co-Diagnostics tests being used at sites run by TestUtah.com. SAC ¶ 59. And it detailed certain data that called into question Co-Diagnostics' test efficacy, compiling sources and information that the company had not previously made available to the public. *Id.*

For example, the Tribune Article detailed that a doctor in Utah involved with the testing there became concerned when only 2% of symptomatic patients were testing positive with Co-Diagnostics' tests while 5% of patients were testing positive at other sites in Utah using other tests. *Id.* ¶¶ 67-68. This suggested that Co-Diagnostics tests were only accurately reporting ***half*** the COVID-19 cases. *Id.* And other news articles also reported trouble with Co-Diagnostics' tests in Iowa. *Id.* ¶ 78, Ex. C (June 13, 2020 New Yorker Article).

D. Co-Diagnostics Makes Material Misstatements to Contain the Fallout

Aware of the mounting concern of medical professionals and its effect on Co-Diagnostics' share price and prospects for future government contracts, Co-Diagnostics decided to go on the offensive. *Id.* ¶ 60. Instead of truthfully and accurately discussing the efficacy of its test, it made two misleading statements to create the false impression that it had a perfect test.

Misleading Statement No. 1: First, in response to criticism of the Co-Diagnostics test in the Tribune Article, Satterfield voluntarily gave a quote to the Tribune reporter. Mr. Satterfield stated that Co-Diagnostics' "COVID-19 tests scored between 99.52% and 100% in evaluations conducted by the FDA and Europe." SAC ¶ 60; Ex. A (April 30, 2020 Salt Lake Tribune Article).

Misleading Statement No. 2: To make matters worse, the next day Satterfield and Co-Diagnostics doubled down. Despite knowing about critical problems with the accuracy of its tests, Co-Diagnostics issued a press release intended to further propagate the false impression that its Covid-19 test was perfect. The press release was titled, "Co-Diagnostics, Inc. Releases COVID-19 Test Performance Data: Consistently ***Demonstrates 100% Sensitivity and 100% Specificity Across Independent Evaluations***." *Id.* ¶ 62 (emphasis added). The press release featured the falsely reassuring words of Co-Diagnostics' Chief Scientist Satterfield:

> In remarking on the test's favorable limit of detection (LOD) results in the evaluations, Brent Satterfield, PhD said, "In diagnostics, the limit of detection or LOD is a single metric that helps inform the key metrics of sensitivity and specificity but is not relevant as a stand-alone data point. Other metrics that are important are availability, ease of use and throughput. In countries where we have been evaluated against other tests, ***we have consistently and repeatedly achieved 100% clinical sensitivity and specificity and you can't do better than that.***"

SAC ¶ 63 (emphasis added).

At bottom, these statements unmistakably were intended to convey a clear impression: Co-Diagnostics' Covid-19 test was 100% accurate and basically perfect, which communicated to the investing public that larger companies with more resources could not "gain" on Co-Diagnostics. Co-Diagnostics' statements had nothing to do with real scientific data and everything to do with buoying its stock price at an artificially high level. *Id.* ¶¶ 7, 69.

These statements were misleading both because they were affirmative misrepresentations

of the accuracy of the company's tests as well as misleading half-truths, in that they omitted material information regarding accuracy problems with the test. *Id.* ¶¶ 61, 64. The market accepted Co-Diagnostics' false claims of 100% accuracy and understood Co-Diagnostics' statements to mean their tests were perfect—sending the company's share price soaring. *Id.* ¶ 69.

E. Co-Diagnostics' Shares Crash when its Misleading Statements Come to Light.

Co-Diagnostics' plan to repress negative reports about its tests seemed to work. *Id.* ¶ 72. By May 14, 2020, the Co-Diagnostics' shares reached an all-time high of $29.72, an extraordinary climb from its less than $1 per share price at the end of 2019. *Id.* However, by that afternoon the Co-Diagnostics' stock price "bubble"—floating on its false information—abruptly popped when its claims of perfect accuracy became unsustainable. *Id.* ¶ 75.

First, on that day the Governor of Iowa announced that it had completed a validation of Co-Diagnostics' tests and found, contrary to Co-Diagnostics' and Satterfield's previous statements, a rating of "95 percent accuracy for determining positives and 99.7 percent accuracy for determining negatives." *Id.* ¶ 77. These results directly contradicted what Satterfield (and Co-Diagnostics) told the investing public on April 30 and May 1. *Id.*

Moreover, the differences between the Iowa's validation results and Co-Diagnostics' claims of accuracy, while seeming quite small, make a massive difference in diagnostic testing. While in most situations, a 99% accuracy rating and a 100% accuracy are functionally equivalent, in diagnostic testing of diseases with a low population saturation, the difference can dramatically affect whether a test has any value to public health officials. *Id.* ¶¶ 66-68, 85. For example, if a diagnostics test has a 98% "specificity" and "sensitivity" rate—two key metrics that factor into a test's accuracy—the practical effect is that there's still a 1 in 3 chance the test will indicate you have COVID-19 even though you do not. *Id.* ¶ 85.

Second, also on May 14, 2020, news outlets reported that Co-Diagnostics "declined to join other major Utah labs in a joint experiment to confirm one another's quality." *Id*. ¶ 75, Ex. B (May 14, 2020 Salt Lake Tribune Article). Moreover, it was revealed that TestUtah's tests [by Co-Diagnostics] "have a higher 'limit of detection' — that is, they require more of the virus to trigger a positive result — than most other coronavirus tests approved for sale in the U.S., according to an analysis by the life sciences publication BioCentury." *Id*. This meant that Co-Diagnostics tests were likely to have a much higher false negative reporting rate, meaning that potentially thousands of infected people were inaccurately told that they did not have the disease—which was consistent with earlier concerns about TestUtah's lower rate of positive test results. *Id.*

Finally, the same day, the United States Food and Drug Administration issued a press release about testing accuracy. *Id.* ¶ 83. Another, much larger drug company (Abbot Laboratories) had created a diagnostic test for Covid-19 that was under increasing public scrutiny for apparent inaccuracy. *Id.* The FDA announced to the public that "***No diagnostic test will be 100% accurate*** due to performance characteristics, specimen handling, or user error, which is why it is important to study patterns and identify the cause of suspected false results so any significant issues can be addressed quickly." *Id.* (emphasis added). This further dispelled Co-Diagnostics' false claims regarding the purported perfect accuracy of its Covid-19 diagnostics test.

Based on these revelations, Co-Diagnostics' stock price began to fall precipitously, closing the day at $22.13 after hitting an intra-day low of $18.35, a greater than 38% decrease within hours. *Id*. ¶ 79. Despite an earnings call later that evening boasting record sales and company performance, Co-Diagnostics' stock price fell to just over $15 per share when the market opened the following day. *Id.* ¶ 84. Those who had bought just before the May, 14, 2020 news lost 50% of their investment in just a few trading hours. *Id*. Soon thereafter, Co-Diagnostics executives

began to exercise low-priced options and sell their shares at artificially high prices—pumped up by Co-Diagnostics' false statements. *Id*. ¶¶ 91-97.

MEMORANDUM OF LAW

I. LEGAL STANDARD

When evaluating a motion to dismiss for failure to state a claim, the Court must accept all well-pleaded allegations as true. *See Adams v. Kinder–Morgan, Inc.*, 340 F.3d 1083, 1088 (10th Cir. 2003). The Court should draw all reasonable inferences in favor of the non-moving party. *Id.* The Court should deny a motion to dismiss when a complaint contains enough facts to state a claim for relief that is plausible on its face. *Id.* Additionally, where, as here, a complaint relies on documents to make its claims, a court may consider those documents. *See GFF Corp*, 130 F.3d at 1384-85; *see also In re SunEdison, Inc. Securities Litigation*, 300 F. Supp. 3d at 487 n. 7; *Evanston Police Pension Fund*, 411 F. Supp. 3d at 593.

II. THE PLAINTIFF HAS PROPERLY PLED ITS SECURITIES FRAUD CLAIM

In Count I, the Plaintiff has asserted a cause of action against Defendants Co-Diagnostics and Satterfield for material misrepresentations or omissions for violation of Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5. Section 10(b) forbids the use, in connection with the sale of securities, of any "manipulative or deceptive device or contrivance" in contravention of the SEC's rules. *See* 15 U.S.C. § 78j(b). SEC Rule 10b-5, in turn, makes it unlawful in connection with the purchase or sale of any security "[t]o employ any device, scheme, or artifice to defraud;" "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statement made ... not misleading;" or "[t]o engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person." *See* 17 C.F.R. § 240.10b-5.

To plead securities fraud under Rule 10b-5, a plaintiff must allege: (1) a material

misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation. *Matrixx Initiatives, Inc., v. Siracusano*, 563 U.S. 27, 38 (2011). The first two elements—material misrepresentation and scienter—are subject to a heightened pleading standard. 15 U.S.C. §§ 78u-4(b)(1), 78u-4(b)(2).

The Defendants motion to dismiss only argues that the first and second elements have not been satisfied. As shown below, the Plaintiff has properly pled these elements. *First*, the pleading properly alleges two specific material misstatements that form the basis for the claim: Satterfield's April 30th comments to the Salt Lake Tribune and Co-Diagnostics' May 1st press release regarding the accuracy of Co-Diagnostics' Covid-19 tests. *Second*, the Complaint clearly raises a "strong inference of scienter," *see* 15 U.S.C. § 78u-4(b)(2), alleging that Defendant Satterfield knew his statements were misleading when he made them, or was reckless in making them, because news reports revealed that Co-Diagnostics' tests were not 100% accurate. *Finally*, the Plaintiff does not allege a duty to correct, as this is a direct fraud case.

A. <u>The Plaintiff Has Sufficiently Alleged a Material Misstatement</u>

The Plaintiff has satisfied its burden to plead a material misstatement or omission of fact. The Defendants appear to raise four arguments regarding this element of the Plaintiff's claim: (1) that the Complaint is a so-called "puzzle pleading" because the Defendants cannot decipher the alleged misrepresentations at issue, *see* Motion at 14-15, (2) that the alleged misrepresentations were technically true statements and thus, cannot form the basis the claim, *id*. at 12-14, (3) that the Plaintiff has not alleged why the statements at issue are false, *id*. at 16, and (4) the Plaintiff has not alleged a duty to correct, *id.* at 16-20. These are all baseless arguments.

i. The Plaintiff Specifically Identifies Two Misrepresentations

As an initial matter, the Complaint is a not a "puzzle-pleading." A puzzle pleading is "voluminous," verbose, and forces a court to sift through hundreds of pages of allegations to locate misleading statements and the reasons they are misleading. *See Rumbaugh v. USANA Health Scis., Inc.*, 2018 WL 5044240, at *4 (D. Utah Oct. 17, 2018). That is not the case here.

The Complaint here is concise and very clearly identifies two material misstatements by the Defendants on April 30, 2020 and May 1, 2020, both intended to create the false impression that Co-Diagnostics had a perfect (or nearly perfect) diagnostic test. The misstatements are:

Misleading Statement No. 1: In response to criticism of the Co-Diagnostics test, Satterfield told a reporter that the company's "COVID-19 tests scored between 99.52% and 100% in evaluations conducted by the FDA and in Europe." SAC ¶ 60; Ex. A (April 30, 2020 Salt Lake Tribune Article).[2] The Complaint refers to this statement as "misleading" and "creating a false impression"—thus clearly alleging it is a misrepresentation. SAC ¶¶ 60-61.

Misleading Statement No. 2: Despite knowing about critical problems with the accuracy of Co-Diagnostics' Covid-19 tests, the company issued a press release intended to create the false impression that the diagnostic test was 100% accurate. The press release stated:

> Co-Diagnostics, Inc. Releases COVID-19 Test Performance Data: ***Consistently Demonstrates 100% Sensitivity and 100% Specificity*** Across Independent Evaluations … In countries where we have been evaluated against other tests, we have consistently and repeatedly achieved 100% clinical sensitivity and specificity and

[2] Defendants also argue that this statement was not attributable to Satterfield and was a "paraphrase" of his statement. Mot. at 14. Defendants' argument is meritless. The article reads "[Satterfield] added that Co-Diagnostics' COVID-19 tests scored between 99.52% and 100% in evaluations conducted by the FDA and in Europe." Ex. A (April 30, 2020 Salt Lake Tribune Article). Here, the reporter did not pull the numbers out of thin air; Satterfield clearly stated those numbers, intending that they be shared with the investing public.

you can't do better than that.

SAC ¶¶ 62-63 (emphasis added). The Complaint made clear the statements in the press release are misrepresentations at issue in the claims. *Id*. ¶ 64 ("press release ***materially misstated the accuracy*** of the Company's Covid-19 tests and ***omitted material information*** that the Company's tests haveproblems with their accuracy and are significantly less than 100% accurate.") (emphasis added).

These allegations regarding these misstatements were then incorporated into Count I. *See* SAC ¶ 106; *see also S.E.C. v. Goldstone*, 952 F. Supp. 2d 1060, 1222 (D.N.M. 2013) (rejecting argument that complaint for securities fraud was a puzzle pleading where the claims incorporated preceding paragraphs). Thus, the Complaint is not a puzzle pleading.

ii. The Defendants Statements were Material Misrepresentations That Misled Investors

The Plaintiffs also have properly pled that the statements at issue were material misstatements. It appears the Defendants argue that the two misstatements at issue are true statements that do not support a securities fraud claim and that the Plaintiff has not pled why the statements are false. These contentions are wrong.

Under the PSLRA, a securities fraud claim must "specify each statement alleged to have been misleading, the reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u–4(b)(1)(B).

In relevant part, a defendant can misrepresent a material fact to investors when it issues a literally true statement that, when viewed in context, misleads investors. *See Operating Local 649 Annuity Trust Fund v. Smith Barney*, 595 F.3d 86, 92 (2d Cir. 2010) ("The veracity of a statement or omission is measured not by its literal truth, but by its ability to accurately inform rather

than mislead prospective buyers"). "Some statements, although literally accurate, can become, through their context and manner of presentation, devices which mislead investors. For that reason, the disclosure required by the securities laws is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead prospective buyers." *In re Convergent Techs. Sec. Litig.*, 948 F.2d 507, 512 (9th Cir. 1991). *See also McMahan & Co. v. Wherehouse Entm't, Inc.*, 900 F.2d 576, 579 (2d Cir. 1990) ([W]hen read as a whole, the defendants' representations connoted a richer message than that conveyed by a literal reading of the statements. The central issue … is not whether the particular statements, taken separately, were literally true, but whether defendants' representations, taken together and in context, would have mislead a reasonable investor"); *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 153 (2d Cir. 2013) ("Even a statement which is literally true, if susceptible to quite another interpretation by the reasonable investor may properly be considered a material misrepresentation.").

Indeed, "[t]he law is well settled that so called 'half truths'--literally true statements that create a materially misleading impression--will support claims for securities fraud. *SEC v. Nutra Pharma Corp.*, 450 F. Supp. 3d 278, 289 (E.D.N.Y. 2020); *see also Lusk v. Life Time Fitness, Inc.*, 213 F. Supp. 3d 1119, 1129 (D. Minn. 2016). "A statement can [ ] be misleading, though not technically false, if it amounts to a half-truth by omitting some material fact." *In re Philip Morris Int'l Inc. Sec. Litig.*, 437 F. Supp. 3d 329, 349 (S.D.N.Y. 2020) (citation omitted).

As alleged in the Complaint, the two statements at issue were misleading under two theories pled by the Plaintiff: (i) they were affirmative and explicit misrepresentations of the accuracy of Co-Diagnostics' tests as well as (ii) misleading half-truths that omitted material information regarding problems with the accuracy of the tests. SAC ¶¶ 60-61, 62-64.

Co-Diagnostics Made Affirmative Misrepresentations About the Efficacy of Its Test

First, the statements at issue were affirmative misrepresentations that misled investors. To

be sure, when the May 1st press release is read as a whole, and in the context in which it was issued (to rebut criticisms from medical professionals as reported by a major Utah newspaper), the message conveyed is clear: the Defendants were telling customers and investors that the Co-Diagnostics' Covid-19 test was 100% accurate, as purportedly backed-up by certain field data. The intent to convey this impression is unmistakable. The press release is entitled "COVID-19 Test Performance Data: ***Consistently*** Demonstrates 100% Sensitivity and 100% Specificity Across Independent Evaluations" and Satterfield said, "***you can't do better than that.***" Notably, in their motion, Defendants ignore the significant latter statement by Satterfield, which was meant to create the false impression that Co-Diagnostics had a 100% accurate test.

Plaintiff alleges that reasonable investors understood Satterfield to be saying the test was 100% accurate—which was false. SAC ¶ 69. For example, immediately after Satterfield issued the release, various investment analysts issued news releases sating that Co-Diagnostics' test were 100% accurate. *Id.* Moreover, the FDA, based on market statements of "100% accurate testing", felt compelled on May 14, 2020 to issue a bulletin stating that ***"[n]o diagnostic test will be 100% accurate"***. *Id*. ¶ 83. And doctors subsequently reviewing Co-Diagnostics' claims that its tests were 100% accurate after the filing of this action called them—literally—"laughable" from a scientific perspective. *Id*. ¶ 65.

The Defendants submit a cynical argument on this issue—one the Court should easily see through. They contend that the misstatements at issue were technically true and, thus, are not actionable. *See* Motion at 12-14. Supporting this faulty assertion, they note that the press release did not make a generalized claim about the accuracy of Co-Diagnostics' tests. *Id*. at 12 ("representations that its Covid-19 tests were '100% accurate'…never actually appears in the Press Release…). Rather, they say, the press release only addressed some limited Covid-19 test

performance data, for which a link was provided, and that data is not alleged to be false. *Id*. at 13-14. But they completely ignore the well-settled law cited above and applicable here, prohibiting defendants from misleading investors through literally accurate statements (if they are, in fact, accurate as Co-Diagnostics asks the Court to assume) that, in context, misinform and deceive investors. *See supra* at 13-14. That is a conspicuous and fatal omission in their motion. In short, the Defendants ask the court to give companies and executives license to manipulate investors through deceiving half-truths. But that is not the law.

The sole case cited by the Defendants on this issue is *In re FX Energy, Inc. Sec. Litig*., 2009 WL 1812828 (D. Utah June 25, 2009). That case does not help them. There, the plaintiffs alleged that press releases issued by the company misrepresented that it used modern 3D technology to drill oil wells and that the statement was false because the defendant used 2D technology. The court dismissed the case, because it could not find "any statements that reasonably imply" that defendant was using the 3D technology and that none of the "press releases or slide presentations made during the relevant period can reasonably read to imply" that defendant was using 3D technology. *Id.* at *7-8. *FX Energy* is thus different than this case, where the Defendants made misleading statements based on half-truths and where, based on their context, Satterfield's statements ***can*** reasonably be read to convey that the test was a 100% accurate.

Turning to the issue the falsity of the statements at issue, contrary to Defendants' assertions, the Complaint also adequately alleges that the Defendants' intended message—that the Covid-19 test was 100% accurate—was simply ***not*** true. The Complaint alleges that medical professionals in both Utah and Iowa raised serious concerns about the accuracy of the test, and that Satterfield was aware of these concerns prior to releasing his April 30 and May 1 statements. Indeed, he issued the statements as a direct retort to the April 30 Tribune Article (which revealed

internal emails calling the use of Co-Diagnostics' test a potential "public health disaster") and then in a more aggressive strategic press release just one day later.

Moreover, data released a few days after Satterfield made his claims of 100% accuracy further confirmed the falsity of his claim. On May 14, the Governor of Iowa explained that state health officials had run their own validation tests, finding that Co-Diagnostics tests only correctly identified true positives 95% of the time, a far cry from the 100% claim touted by Satterfield, and materially less accurate test than a 100% accurate test. SAC ¶ 77. A few months after the press release, Satterfield conceded that his claims of 100% accuracy were not true. *Id*. ¶ 78. Satterfield could have pulled back the statements he made in April and May, but his company's stock was surging. By December 2020, when Satterfield's contradictory statements were released to the public, the stock had slid to around $10-$11 per share (today it is sitting between $8-$9 per share).

Further, Satterfield's message of 100% accuracy was not only false based on the field data (*i.e.* the company received experimental data that the tests were not 100% accurate), but his message can never be true in the diagnostic testing world. As a sophisticated scientist who develops diagnostic tests, Satterfield knew that a perfectly accurate COVID-19 test does not exist in the real world. SAC ¶ 61. His message was false on its face. Both the FDA and medical experts have counseled the public that no diagnostic test can ever be perfectly accurate, contradicting Satterfield's message to the public and demonstrating the facial falsity and recklessness of his statements. SAC ¶¶ 65, 83.

Co-Diagnostics Made Material Omissions of Fact

Second, the misstatements at issue not only contain affirmative misrepresentations, but they are misleading because they omit material information about Co-Diagnostics' tests. As noted, "[a] statement can be misleading, though not technically false, if it amounts to a half-

truth by omitting some material fact." *In re Philip Morris*, 437 F. Supp. 3d at 349. Once a party chooses to make a statement on a material issue, it then has a duty to be both complete and accurate; a party will be liable under the securities laws when it speaks on an important matter but fails to make the additional disclosures "necessary to avoid rendering the statements misleading." *Hall v. Children's Place Retail Stores, Inc.*, 580 F. Supp. 2d 212, 226 (S.D.N.Y. 2008).

Once a company chooses to "tout" a product or its likelihood of success in reaching a goal, it is then bound to do so in a manner that does not mislead investors about the product or about the company's likelihood of success in reaching that goal. *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 707–08 (9th Cir. 2016) ("Once defendants chose to tout [their drug's] likely approval by referencing allegedly positive animal and preclinical studies, they were bound to do so in a manner that wouldn't mislead investors as to potentially negative information within [defendants'] possession. [Defendant's] failure to inform the market about the risk of non-approval or delayed approval based on the FDA's concerns about the Rat Study was an extreme departure from the standards of ordinary care that presented a danger of misleading buyers or sellers that was either known to [Defendant] or was so obvious that [Defendant] must have been aware of it.") (cleaned up); *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 987 (9th Cir. 2008) ("Had defendants released no backlog reports, their failure to mention the stop-work orders might not have misled anyone. But once defendants chose to tout the company's backlog, they were bound to do so in a manner that wouldn't mislead investors as to what that backlog consisted of.").

Matrixx, first referenced above, presents a factual scenario very similar to what occurred here and is instructive on when a failure to disclose adverse information is actionable. In *Matrixx*, the defendant sold a popular cold remedy called Zicam that constituted 70 percent of its sales. 563 U.S. at 47. The Dow Jones Newswire issued a report stating that the FDA planned to investigate

customer complaints that Zicam was causing a loss of smell. *Id.* at 34. In response to this news report, the defendant issued a press release calling the link between the drug and loss of smell "completely unfounded and misleading." *Id.* The press release also stated that there were no reports of loss of smell in certain clinical trials. *Id.* The Supreme Court held that the press release was misleading by omission because the defendant failed to inform the investors of information it had regarding the biological link between loss of smell and its drug, which, as the Court stated, was necessary in order to make the "statements made [in the press release], in light of the circumstances under which they were made, not misleading." *Id.* at 47.

As in *Matrixx*, the Defendants' statements at issue in this case were misleading because the Defendants did not qualify the assertion of 100% accuracy, did not inform the public of results showing that Co-Diagnostics' tests had a higher false negative rate, or inform the public that medical professionals had called the 100% accuracy claims into question. SAC ¶¶ 74-77. Under controlling case law, once Satterfield chose to speak about validation tests run on the Co-Diagnostics' Covid-19 test, he was required to do so in a non-misleading way—which required him to explain alternative and material adverse facts related his statements. *Schueneman*, 840 F.3d at 707–08. *Berson*, 527 F.3d at 987. Having failed to do so, his statements were misleading.

As a result, the Plaintiff has sufficiently alleged that Satterfield's statements were misleading because the statements were either affirmative misrepresentations or actionable half-truths. At this stage of the proceedings, with inferences drawn in favor of the Plaintiff, the Court must reject the Defendants' arguments that the first element of this claim is not satisfied.

iii. Plaintiff is Not Pursuing a Duty to Correct Theory

The Defendants argue that the Plaintiff has not alleged a duty to correct—either its own statements or the statements of third parties. *See* Motion at 16-20. This is a red herring because the Plaintiff has alleged a direct fraud case, based on knowing misrepresentations.

"The most common and obvious method" of proving an actionable misstatement is "by demonstrating that the defendant fraudulently made a statement of material fact or omitted a fact necessary to prevent a statement from being misleading." *Stransky v. Cummins Engine Co., Inc.*, 51 F.3d 1329, 1331 (8th Cir. 1995). However, there is another "avenue" to plead a material misstatement which "applies when a company makes a historical statement that, ***at the time made, the company believed to be true***, but as revealed by subsequently discovered information actually was not. The company then must correct the prior statement within a reasonable time." *Id.* (emphasis added). But here, the Plaintiff alleges that the company did not believe (or at least they should not have believed) its message of 100% accuracy was true when it issued the Press Release. SAC ¶¶ 61, 64. As a result this is a straightforward fraud case and not a duty to correct case. The Court should therefore set aside this argument—it addresses a non-issue here.

B. <u>The Plaintiff Has Sufficiently Alleged Scienter</u>

To decide whether a plaintiff has alleged scienter, a court must determine whether a plaintiff has alleged enough "facts giving rise to a strong inference" of scienter. *City of Philadelphia v. Fleming Cos., Inc.*, 264 F.3d 1245, 1258 (10th Cir. 2001). Scienter is a "mental state embracing intent to deceive, manipulate or defraud" or "knowing or intentional conduct." *Id.* A plaintiff can also satisfy scienter by showing that a defendant was reckless in making a statement; recklessness means a departure from "the standards of ordinary care, and which presents a danger of misleading [investors] that is either known to the defendant or is so obvious that the actor must have been aware of it." *Id.*

In determining whether the pleaded facts give rise to a strong inference of scienter, the Court must compare culpable explanations for a defendant's conduct with nonculpable explanations for his conduct. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324

(2007). The "inference that defendant acted with scienter need not be irrefutable, *i.e.*, of the smoking-gun genre, or even the most plausible of competing inferences." *Id.* "A complaint will survive ... only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id. See also Pirraglia v. Novell, Inc.*, 339 F.3d 1182, 1188 (10th Cir. 2003) ("this process does not involve a "weighing" of the plaintiff's suggested inference against other inferences. Faced with two seemingly equally strong inferences, one favoring the plaintiff and one favoring the defendant, it is inappropriate for us to make a determination as to which inference will ultimately prevail, lest we invade the traditional role of the factfinder"). When considering this question, "the court's job is not to scrutinize each allegation in isolation but to assess all the allegations holistically." *Id.*

There are five categories of alleged facts, when considered together, that create a strong inference that Satterfield knew his statements were misleading or was reckless in making them.

First, before he made both his statements on April 30 and May 1, suggesting the COVID-19 test was a perfect test, Satterfield possessed actual information of serious critiques of the Co-Diagnostics test. When medical professionals tell a company about problems with its product, and the company nonetheless continues to make confident statements about the product, courts have inferred scienter and falsity. *See Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 350 (E.D. Pa. 2014) (finding inference of scienter where defendant touted confidence in his product despite possessing adverse information from a regulatory body about its product); *In re MannKind Sec. Action*, 835 F. Supp. 2d 797, 811 (C.D. Cal. 2011) ("When the FDA tells a company about problems with a product, and the company nonetheless continues to make confident predictions about a product, courts have inferred scienter and falsity.").

Here, it is strongly inferred that Satterfield had adverse information about Co-Diagnostics'

test as early as mid-April (or sooner) that was not generally available to the investing public. As reported on April 30, ***in an article Satterfield was quoted in***, on April 14th, a doctor in Utah e-mailed others involved in the testing: "What alarms me the most is that they [Co-Diagnostics] are expanding collection and testing with these unknowns about how their test performs. If correct, I urge you to halt their testing until we understand why their results differ so much from what other labs are reporting … This is a potential public health disaster…" SAC ¶ 59, Ex. A (April 30, 2020 Salt Lake Tribune Article). A public news article released in June revealed that on April 27, health officials in Iowa e-mailed about concerns with the test and noted that "[Co-Diagnostics] is not supporting [test validation] as they should." SAC ¶ 78 n. 9; Ex. C (June 13, 2020 New Yorker Article). At the very latest, Satterfield became aware of serious concerns with the Co-Diagnostics test by April 30th, when the Tribune Article was released bearing his quote and name. *See* SAC ¶¶ 59- 60; Ex. A (April 30, 2020 Salt Lake Tribune Article) (responding to questions about the alleged inaccuracies of his test).

Despite this adverse information, Co-Diagnostics issued a press release on May 1, just one day after the release of the Tribune Article, ***with another Satterfield quote***, suggesting the test was perfect, failing to disclose or even discuss any adverse information he knew about the accuracy of the tests, and misleadingly claiming "you can't do better than that." SAC ¶ 63. Satterfield knew investors would want this adverse information, and he knew that by failing to discuss the totality of the information, investors would be misled. *See City of Philadelphia*, 264 F.3d at 1258 (courts find scienter when a "defendant must have been aware both of [the omitted information's] materiality and that its non-disclosure would likely mislead investors.").

Second, Satterfield's background is important here and helps demonstrate why he knew or should have known that his statements were highly misleading. Satterfield is a Ph.D.-level scientist

who develops and invented diagnostic tests. SAC ¶ 61. While most reasonable investors, even savvy ones, are not scientists and likely do not understand the scientific foundations of diagnostic testing, Satterfield surely does. As one doctor said, any claim of 100% accuracy of a diagnostic test is "laughable." *Id*. ¶ 65; *see also id*. ¶ 83 (FDA announcement that "[n]o diagnostic test will be 100% accurate"). Satterfield cannot claim, as he now does, that he made a good faith error and simply meant to convey truthful information. He is a scientist who understood or, at least, should have understood that the message he was conveying was misleading to investors. *See Frater*, 996 F. Supp. 2d at 350 (finding inference of scienter because defendants who were "sophisticated scientists" did not have any good faith explanations for why they heralded "scientific results" which they knew were the "product of empirically faulty procedures").

Third, the timing of the misstatements further shows why Satterfield knew the statement was misleading when he made it. On the heels of serious criticism, indeed the day after the April 30 article, Co-Diagnostics issued a press release to counter critiques of its test. The timing of the release shows that it was designed to mislead rather than to convey truthful information. *See Matrixx*, 563 U.S. at 49 (finding scienter when company issued Press Release misleadingly countering bad facts day after news report regarding bad facts).

Fourth, Satterfield had a unique motive and a suitable opportunity to mislead. Courts must look to the totality of the pleadings to determine whether a plaintiff's allegations permit a strong inference of fraudulent intent; allegations of motive and opportunity may be important to that totality but are typically not sufficient themselves to establish scienter. *See City of Philadelphia*, 264 F.3d at 1261. In the securities context, "motive" entails concrete benefits that could be realized by one or more of the false statements and wrongful non-disclosures alleged, and "opportunity" entails the means and likely prospect of achieving concrete benefits by the means alleged. *Id.*

While motives shared by most companies do not ordinarily support an inference of intent, motives that are unique to a company will support an inference of scienter. *Id.* at 1269. Here, Co-Diagnostics had a specific motive to mislead. Prior to developing its COVID-19 diagnostic test, it was a penny stock company with no customers and no prospects for future success. SAC ¶¶ 45-48. But, when it developed one of the first COVID-19 diagnostic tests, it saw its stock soar, entered into lucrative contracts, and had become an almost $800 million company. *Id.* ¶ 58. Faced with specific assertions that its Covid-19 test was faulty—and the potential fall-out if those claims went without rebuttal, Co-Diagnostics would have suffered an immense setback.

Moreover, while Co-Diagnostics was a first mover in the COVID-19 diagnostic testing space, it knew larger, more reputable companies were nipping at its heels in an arms race to have the most effective test on the market, when even tiny rates of failure in lab settings can have large public health implications. SAC ¶¶ 86-88. Stating that your test is 100% accurate and that you "can't do better than that" created the false impression that Co-Diagnostics was first, best, and would remain so regardless of subsequent developments by competitors.

Additionally, Co-Diagnostics had a uniquely suitable opportunity to mislead. At the beginning of the pandemic, the public was confused and distressed about the disease, including how it spread, how severe it was, and, importantly, how to test for it. And there was a serious urgency to ramp up mass testing so that individuals and public authorities could make informed decisions about mitigating the spread and treating the virus. SAC ¶ 2. Simply put, we did not have a lot of information on the virus or how to test it. Satterfield capitalized on this situation. He realized that the pandemic presented an evolving situation and that by presenting his own set of data he could wrest control of what was becoming an increasingly bad narrative for Co-Diagnostics.

Fifth, Co-Diagnostics "declined to join other major Utah labs in a joint experiment to confirm one another's quality" which suggests that it knew and knows its tests are not nearly 100% accurate but did not want independent testing to confirm this bad fact. SAC ¶ 75. If Satterfield truly believed the veracity of his statements, the company would have agreed to test validation. A plausible inference from their refusal to joint validation test is that the company knew that any tests would confirm exactly what Plaintiff is saying: the tests were not 100% accurate.

Taken together, all these alleged facts show that Satterfield knew his statements were misleading when he made them. At the very least, the facts described above create a strong inference that Satterfield acted recklessly. He had knowledge of key facts—*i.e.*, criticisms of his test showing it was less than 100% accurate—that was so obviously material that he must have been aware that its non-disclosure would likely mislead investors.

Importantly, the Defendants have not submitted any nonculpable explanations for Satterfield's statements. As best we can tell, the Defendants argue that Satterfield did not intend to mislead, he thought the underlying data was accurate, and he merely wanted to convey truthful data to the public. But the much stronger explanation, and one supported by the allegations, which govern here, is that in the face of mounting criticism of his test, and not waiting to lose lucrative contracts and see his company become a penny stock once more, Satterfield designed a Press Release to falsely suggest to investors that the test was perfect.[3]

As a result, the Plaintiff has met its burden by offering an inference of scienter that is certainly "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs,* 551 U.S. at 326.

[3] Because the SAC adequately alleges that Satterfield, the founder, and chief scientist at Co-Diagnostics, had the scienter to defraud, "those allegations are also sufficient to allege scienter to defraud on behalf of [the company itself]." *Adams,* 340 F.3d at 1106.

III. THE PLAINTIFF HAS ADEQUATELY ALLEGED CONTROL VIOLATIONS

In Count II, the Plaintiff brought a claim for control person liability against several Co-Diagnostics executives under Section 20 of the Exchange Act. To state a *prima facie* case of control person liability, the plaintiff must establish (1) a primary violation of the securities laws and (2) control over the primary violator by the alleged controlling persons. *Adams*, 340 F.3d at 1107. The Defendants argue that the Plaintiff has not established the first element—a primary violation of the securities law. But as shown above, Plaintiff has successfully pled primary violations by Defendants Satterfield (acting as an agent of Co-Diagnostics) and Co-Diagnostics.

The Defendants do *not* make any arguments as to the second element. To satisfy the second element, a plaintiff must plead facts which indicate that each person had "possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract or otherwise." *Id.* Plaintiff has adequately alleged that the individual Defendants are all liable as control persons. SAC ¶¶ 28-30, 112. Dwight Egan was the CEO of the company and Satterfield was the Chief Science Officer, and as officers, they exercised day to day control over the company. Plaintiff has also adequately alleged that Directors James Nelson, Eugene Durenard, Edward Murphy, Richard Serbin, and Reed Benson also exercised control over the company and are thus liable as control persons. *Id.*

And since this issue was not raised by Defendants in its motion and it cannot be raised in the reply brief, the motion should be denied as to Count II. *See Galindo v. Asset Recovery Tr.*, No. 2:07CV868 DS, 2008 WL 3851434, at *2 (D. Utah Aug. 12, 2008)

CONCLUSION

For the reasons stated above, the Court should deny Defendants' motion to dismiss.

Plaintiff has adequately alleged material misrepresentations and scienter.

DATED: June 9, 2021

ARMSTRONG TEASDALE

/s/ D. Loren Washburn
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